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EXAMINER	
GOLDBERG, JEANINE ANNE	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 03/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

HC

Office Action Summary	Application No.	Applicant(s)	
	10/049,329	KIMBERLY ET AL.	
	Examiner	Art Unit	
	Jeanine A Goldberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *9-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/23/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the papers filed December 27, 2004. Currently, claims 1-11 are pending. Claims 9-11 have been withdrawn as drawn to non-elected subject matter.

Election/Restrictions

2. Applicant's election without traverse of Group I, Claims 1-8 in the paper filed December 27, 2004 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Priority

3. This application is a 371 of PCT/US/00/21769, filed August 9, 2000 and claims benefit to provisional application 60/147,838, filed August 9, 1999 and 60/153,869, filed September 14, 1999.

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Drawings

4. The drawings are acceptable.

Claim Rejections - 35 USC § 101

5. Claims 7-8 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112-Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a process for determining IL-10 promoter alleles specific to an individual human and a process for predicting a human immunoresponse to a disease.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2b 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed". Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. In *The Regents of the University of California v. Eli Lilly* (43 USPQ2b 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...' required a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

The claims are drawn to a single nucleotide polymorphism in the DNA encoding IL-10 –1.2 to –4.0 kb. As provided in Example 11, no common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, a SNP at –3575, -2849, -2763 alone is insufficient to describe the genus. The instant specification specifically states that the IL-10 promoter is highly polymorphic (page 2, lines 12-15).

There is no description of the mutational sites that exist in nature and there is no description of how the structure of a SNP at –3575, -2849, -2763 relates to the structure of any strictly neutral alleles. The general knowledge in the art concerning variants does not provide any indication of how the structure of one allele is representative of unknown alleles. The claims broadly encompass additional SNPs or genotypes which have not been disclosed. Genotype is a very broad term which encompasses, SNPs, mutations, deletions, insertions translocations, microsatellites, and splice variants, for example. The nature of alleles is such that they are variant structures, and in the present state of the art the structure of one does not provide guidance to the structure of others. The common attributes are not described. One of skill in the art would conclude that applicant was not in possession of the claimed genus because a description of only three members of this genus is not representative of the variants of the genus and is insufficient to support the claim.

With respect to Claims 4-6, neither the specification nor the claims describe position –3575, -2849, -2763. The specification nor the claims provide any reference point for the positions or provide any sequence from which these positions are found. The specification nor the claims have described the positions –3575, -2849, -2763.

Accordingly, Applicants have not adequately disclosed the relevant identifying characteristics of a representative number of species within the claimed genus.

Claim Rejections - 35 USC § 112-Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detecting polymorphisms as –1082, -819, -592, does not reasonably provide enablement for predicting a human immunoresponse to a disease or predisposition to a disease based upon polymorphisms in the IL-10 promoter. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention and breadth of claims

The claims are drawn to a process for determining IL-10 promoter alleles specific to an individual human and a process for predicting a human immunoresponse to a disease.

The invention is in a class of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Fed. Cir. 2001).

The unpredictability of the art and the state of the prior art

The art teaches a wide variety of studies which analyze whether mutations in IL-10 promoter are associated with diseases.

Keijsers et al (Arthritis and Rheumatism, Vol. 40, 9 Suppl: S179, September 1997; 891) teaches IL10 polymorphisms in relation to production and rheumatoid arthritis (RA). Keijsers teaches analyzing –1082, -819, -592. Keijsers concludes that the IL10 promoter polymorphisms are not associated with disease susceptibility and most likely not with severity in RA.

Coakley et al. (Br. J. of Rheumatology, Vol. 37, pages 988-991, 1998) teaches studying whether promoter polymorphisms associated with variation in IL10 production are relevant to the development tof RA or Felty's syndrome (FS). Coakley teaches that there is no significant differences in allele or haplotype frequencies and no association between FS or RA and –533 or –1120 polymorphisms.

Preiss et al. (Human Immunol. Vol. 60; Suppl 1: S104, April 1999) teaches variations between haplotype frequencies in populations from German blood donors and Great Britain were presented.

Tountas et al. (Gastroenterology, Vol. 116, Suppl 4 Pt. 2, G3617, April 1999) teaches ethnic association of three polymorphisms in the IL-10 promoter and inflammatory bowel disease (IBD). Tountas teaches that no association was detected between each of the three polymorphisms and either Ulcerative Colitis (UC) or Crohn's disease (CD). In the C/J group, there was no association between the three polymorphic sites and either UC or CD as a whole. When we divided the IBD patients into J and non-J subgroups, a significant association between carriage of the rare alleles of –819 and –592 and CD was detected in the non-J/C group.

Koch et al. (Atherosclerosis, Vol. 159, pages 137-144, 2001) teaches a lack of association between polymorphisms of IL-10, TNF-alpha, and TNF-beta that neither separately nor in cooperation associated with the risk of coronary artery disease (CAD) and myocardial infarction (MI) (abstract). Koch also warns that the study was performed with individuals of Caucasian origin and it has to be determined separately whether or not the results are valid in populations of other ethnic origin. Koch teaches that in a Chinese population, IL10 promoter allele and haplotype frequencies were found to greatly differ from those in Caucasians (page 143, col. 1).

Ohashi et al. (Southeast Asian J. of tropical Medicine and public Health, Vol. 33, Suppl 3, 5-7, 2002) teaches a lack of association between interleukin-10 gene promoter polymorphism and –1082G/A and severe malaria in Thailand.

Depboylu et al. (Neuroscience Letters, Vol. 342, pages 132-134, 2003) teaches lack of association of interleukin-10 promoter region polymorphisms with Alzheimer's disease.

McGlinchey et al. (J. Mol. Med, Vol. 82, pages 756-761, 2004) teaches that in an Irish population, IL-10 –1082G/A was not found to be associated with ischaemic heart disease (IHD). McGlinchey analyzes possibilities for lack of association. McGlinchey states that there are several potential reasons why an association was not found: 1) the polymorphism was not associated with IHD 2) a type II error where there is an association but the method failed to detect it however, McGlinchey states that the test appears to have power or 3) population heterogeneity and the findings only apply to an Irish population as studied.

Tait et al. (Autoimmunity, Vol. 37, pages 189-194, May 2004) teaches polymorphisms of Interleukin 10 gene are not associated with Graves' disease in the UK.

Guidance in the Specification and Working Examples

The specification teaches that the IL-10 promoter is highly polymorphic. The specification teaches that three known SNPS (-1082, -891, -592) have been identified. The specification teaches that once a new polymorphism has been identified, molecular biology tests are used to haplotype patients for the presence or absence of a given single nucleotide polymorphism (page 6, lines 12-15). The specification teaches that in 52 normal healthy donors phenotypes for high or low IL-10 production, the A allele at nt –3575 ($p<0.001$) and the A allele at nt –2763 ($p<0.01$) are associated with low IL-10 production (page 8, lines 5-10). Further, the A allele at nt –2849 shows a correlation in donors for low IL-10 (page 8, 10-15) but does not teach this is significant. The specification teaches that in the African American cohort, two novel SNP sites were identified that were not polymorphic in any of the 52 Caucasian normal phenotypes (page 10, lines 7-8). The specification analyzes the distribution of SLE patient haplotypes and found they were significantly different from low production normals ($p=0.001$) and essentially the same as the high producers as shown in Table 4. The specification supports the ethnic differences of frequencies of polymorphisms (page 14). The specification provides no clear evidence that the any IL-10 promoter genotype is associated with diseases. The guidance provided by the specification amounts to an invitation for the skilled artisan to try and follow the disclosed instructions to make and use the claimed invention. The specification merely discloses the presence of three new SNPS. The specification specifically teaches that "once a new polymorphism has been identified, molecular biological tests are used to haplotype patients for the presence or absence of a given single nucleotide polymorphism.

Quantity of Experimentation

The quantity of experimentation in this area is extremely large since there is significant number of parameters which would have to be studied. While one could conduct additional experimentation to determine whether, e.g. genotypes or SNPs might be associated with, e.g., a human immunoresponse to a disease, the outcome of such research cannot be predicted and such further research and experimentation are both unpredictable and undue.

The claims are broadly drawn to a SNP or a genotype. The specification and the art have taught particular SNPs identified. However, the claims broadly encompass additional SNPs or genotypes which have not been disclosed. Genotype is a very broad term which encompasses, SNPs, mutations, deletions, insertions translocations, microsatellites, and splice variants, for example. The specification has taught that the IL-10 promoter is highly polymorphic. The specification further teaches that "in our African American cohort, two novel SNP sites were identified that were not polymorphic in any of the 52 Caucasian normals phenotyped for IL-10 production" (page 10, lines 5-10). Thus, the specification and the art support the highly variable genus encompassed by the instant claims. While additional SNPs may be determined, neither the specification nor the art provide any guidance how to determine whether the SNP is present in a particular population or whether the SNP is strictly neutral.

With respect to Claim 2 directed to a SNP which affects IL-10 production. Neither the specification nor the art teach which SNPs which "affect" IL-10 production. The specification fails to provide any teachings or guidance which SNPs affect IL-10 production. The skilled artisan would be required to perform additional, unpredictable and undue experimentation to determine which SNPs increase and which SNPs lower IL-10 production. The prior art teaches that different SNPs affect the IL-10 production

differently. Thus, determining whether the SNP affects IL-10 production is unpredictable.

As exemplified by the art, the association of SNPs with diseases is unpredictable and undue. It is clear from the art that each SNP is not predictably correlated with each disease in every population. For example, the art teaches the IL10 promoter polymorphisms are not associated with disease susceptibility and most likely not with severity in RA; no association with FS or RA; no association with IBD, UC or CD; lack of association with CAD and MI; lack of association with Alzheimer's disease; lack of association with ischaemic heart disease; and Graves' disease.

The claims broadly encompass any immunoresponse to any disease. The claims further require diseases of cancer, viral infection lupus, asthma, allergy, IBD, for example. This broad spectrum of diseases do not appear to share any genetic similarity. The prior art teaches analysis of many of these diseases and a lack of association with Interleukin-10 polymorphisms. It is unpredictable whether alternative mutations would be associated with any or all of these diseases without further and unpredictable experimentation.

Moreover the art teaches that frequencies of the SNPs within various ethnic groups varies and often varies significantly. Therefore, even though an association between a particular ethnic group and a SNP is provided, this is not predictable to each other ethnic group since frequencies of alleles varies significantly. For example, Koch teaches that in a Chinese population, IL10 promoter allele and haplotype frequencies were found to greatly differ from those in Caucasians (page 143, col. 1). Further, McGlinchey proposes that the population heterogeneity exists and the findings only apply to an Irish population as studied.

This would require years of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

Level of Skill in the Art

The level of skill in the art is deemed to be high.

Conclusion

In the instant case, as discussed above, in a highly unpredictable art where new polymorphisms in promoter sequences are not predictably associated with any particular diseases. Further, the prior art and the specification provides insufficient guidance to overcome the art recognized problems related to providing an association between a polymorphism or genotype and a disease. Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of that art, the large quantity of research required to define these unpredictable variables, the lack of guidance provided in the specification, the absence of a working example and the negative teachings in the prior art balanced only against the high skill level in the art, it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 1-2, 4-6 are indefinite because it is unclear as to whether the claims are intended to be limited to method for determining IL-10 promoter alleles or methods of genotyping DNA for SNPs. The claims are drawn to a process for determining IL-10 promoter alleles. However, the final step is one of genotyping DNA. Accordingly it is unclear as to whether the claimed method is for determining IL-10 promoter alleles or a method of genotyping.

B) Claim 3 is indefinite because it is unclear as to whether the claims are intended to be limited to method for predicting a human immunoresponse to a disease or a method for determining clinical outcome for a patient based on a genotype. The claims are drawn to a process for predicting a human immunoresponse to a disease. However, the final step is one of determining clinical outcome for a patient based on a genotype. Accordingly it is unclear as to whether the claimed method is for predicting a human immunoresponse to a disease or a method for determining clinical outcome for a patient based on a genotype.

C) Claims 4-6 are indefinite over the recitation "said single nucleotide polymorphism is in nucleotide -***" because "-3575", for example, does not have any context. The claims does not indicate –3575 of what sequence. Numbering systems in the art vary and it is not clear what –3575 encompasses.

E) Claims 7-8 provides for the use of a single nucleotide polymorphism in an IL-10 promoter genotype to identify susceptibility to a disease, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-2, 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Eskdale (Immunogenetics, Vol. 46, pages 120-128, August 1997).

Eskdale et al. (herein referred to as Eskdale) teaches mapping the human IL10 gene and further characterization of the 5' flanking sequence. Eskdale teaches sequencing 3-4 kb upstream of the transcription initiation site and identification of two

new point mutation in the immediate promoter region. Eskdale teaches sequencing the human IL10 5' flanking region (page 121, col 1). Eskdale teaches analyzing up to position –4082 from the transcription site of the human IL-10 gene (with the base immediately preceding the A of the ATG taken as position –1). With respect to Claim 2, the instant specification teaches that SNPs in the –1.2 to –4.0 inherently affect IL-10 production. Therefore, a method of sequencing these regions would inherently encompass a SNPs which affects IL-10 production. Since Eskdale teaches a method of sequencing the promoter region up to position –4082 and sequencing is a means of genotyping, Eskdale anticipates the instant claim.

10. Claim 3, 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Mok et al. (Arthritis and Rheumatism, Vol. 41, No. 6, pages 1090-1095, June 1998).

Mok et al. (herein referred to as Mok) teaches studying interleukin-10 promoter polymorphisms in southern Chinese patients with systemic lupus erythematosus (SLE). Mok teaches extracting DNA from Chinese patients with SLE and ethnically matched controls in the IL-10 promoter region between –533 and –1120. Mok teaches analyzing the data using chi-square test to study the differences in genotype and haplotype frequencies between SLE patients and controls (page 1091, col. 2). Mok concludes that IL-10 genotypes are strongly associated with certain clinical manifestations of SLE. Mok teaches that "in our local SLE population, certain IL-10 genotypes were strongly associated with renal disease, and therefore may have a role in predicting disease

prognosis. Therefore, since Mok teaches a process for predicting a human immunoresponse to a disease by genotyping, Mok anticipates the instant claims.

Conclusion

11. **No claims allowable.**

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272- 0745.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Central Fax Number for official correspondence is (571) 273-8300.

J. Goldberg

Jeanine Goldberg
Primary Examiner
February 26, 2005